K130094

510(K) SUMMARY
As Required By 21 CFR 807.92

JUN 2 7 2013

According to the requirements of 21 CFR 807.92, the following information provides detail for a determination.

General Information

Submitter Information	Abbot Diabetes Care Inc. 1360 South Loop Road Alameda, CA 94502
Contact Person:	David G. Lambert Senior Regulatory Affairs Specialist
Telephone No.	(510) 749-5105
Fax No.	(510) 864-4791
Date Prepared	January 25, 2013
Device Information:	
Proprietary Name(s)	Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System
Common Name	i) System, Test, Blood Glucose, Over the counter ii) Glucose Dehydrogenase, Glucose iii) Nitroprusside, Ketones (Urinary, Non-quant.)
Classification Name	i) Glucose Test System (21 CFR 862.1345, Product Code NBW) ii) Glucose Test System (21 CFR 862.1345, Product Code LFR) iii) Ketones (Nonquantitative) Test System (21 CFR 862.1435, Product Code JIN) iv) Calculator/data processing module, for clinical use. (21 CFR 862.2100, Product Code JQP)
Predicate Device	Precision Xceed Pro Blood Glucose and β-Ketone Monitoring System, cleared under K080960
Legal Manufacturer:	Abbott Diabetes Care Ltd. Range Road Witney Oxon OX29 0YL UK

Device Description and Technological Characteristics:

The Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System is a microprocessor-controlled devices that algorithmically process electrical current from a (biosensor) test strip to compute a diabetic patient's blood glucose reading. The meter is fabricated from standard electronic components housed in an injection molded plastic case that

offers easy test strip alignment and insertion, and a custom graphic liquid crystal display (LCD). The LCD will display menu prompts, icons, results, and data. The meter also includes a function key for turning the unit on/off and to select functions.

The meter requires 2 user replaceable standard AA cell batteries. The Freestyle Precision Pro meter is calibrated by scanning the lot specific bar code on the test strip foil label. An assay cannot be performed until the barcode information has been recorded.

The meter automatically stores the last 2,500 test results, which may be a combination of blood glucose or glucose control results. These results can be recalled and displayed again. Additionally, the meters can store up to 6,000 Operator IDs or 1,000 Quality Control tests.

Intended Use: Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System

The Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from the finger, and from venous, arterial and neonatal whole blood, and for the quantitative measurement of β - ketone (beta-hydroxybutyrate) in fresh capillary whole blood from the finger and venous whole blood when used within 30 minutes after collection. The Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of a diabetes control program. This system should only be used with single-use, auto-disabling lancing devices.

The system should not be used for the diagnosis of or screening for diabetes.

The Freestyle Precision Pro Blood Glucose Test Strips are for use with the Freestyle Precision Pro Blood Glucose and β-Ketone Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. The Freestyle Precision Pro Blood β-Ketone Test Strips are for use with the Freestyle Precision Pro Blood Glucose and β-Ketone Meter to quantitatively measure β-ketone in fresh capillary whole blood samples drawn from the fingertips.

Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System enables automatic transmission of stored data to a data management system using the docking station (optional), a data upload cable (optional), or wirelessly (optional) in a WiFi enabled facility when the meter and data management systems are properly configured.

Comparison to Predicate Device:

The Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System has equivalent technological characteristics to the Precision Xceed Pro Blood Glucose and β-Ketone Monitoring System (cleared under K080960). The test strip has the same intended use as the predicate test strip.

The similarities between the Freestyle Precision Pro and Freestyle Xceed Pro Blood Glucose and β-Ketone Monitoring Systems are highlighted below:

	Predicate	Proposed Device
Characteristic	**Precision Xceed Pro Blood Glucose and β-Ketone Monitoring System**	**Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System**
Blood Glucose Strip Specifications		
Test Strip Enzyme	Glucose Dehydrogenase (NAD dependent)	Same
Glucose Range	20-500 mg/dL	Same
Operating Temperature	59°-104°F	Same
Operating Humidity	10-90%	Same
Sample volume (Glucose)	0.6 µl	Same
Data storage	2,500 patient results 1,000 control test results	Same
Power source	2 AA batteries	Same

The differences between the Freestyle Precision Pro and Freestyle Xceed Pro Blood Glucose and β-Ketone Monitoring Systems are highlighted below:

	Predicate	Proposed Device
Characteristic	**Precision Xceed Pro Blood Glucose and β-Ketone Monitoring System**	**Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System**
Indications for Use	The Precision XCeed Pro Blood Glucose and β-Ketone Monitoring System is intended for *in vitro* (outside the body) diagnostic use for the quantitative measurement of glucose (D-glucose) in fresh capillary whole blood samples. The Precision XCeed Pro System is for home (lay user) or professional use. The system is not for use in diagnosing diabetes mellitus, but is to be used as an aid in monitoring the effectiveness of diabetes control programs. Healthcare professionals may also use the product for the quantitative measurement of glucose in venous, arterial, or neonatal whole blood and ketone in venous blood, provided the sample is used within 30 minutes after collection.	The Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from the finger, and from venous, arterial and neonatal whole blood, and for the quantitative measurement of β - ketone (beta-hydroxybutyrate) in fresh capillary whole blood from the finger and venous whole blood when used within 30 minutes after collection. The Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of a diabetes control program. This system should only be used with single-use, auto-disabling lancing devices. The system should not be used for the diagnosis of or screening for diabetes. The Freestyle Precision Pro Blood Glucose Test Strips are for use with the Freestyle Precision Pro Blood Glucose and β-Ketone Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. The Freestyle Precision Pro Blood β-Ketone Test Strips are for use with the Freestyle Precision Pro Blood Glucose and β-Ketone Meter to quantitatively measure β-ketone in fresh capillary whole blood samples drawn from the fingertips. Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System enables automatic transmission of stored data to a data management system using the docking station (optional), a data upload cable (optional), or wirelessly (optional) in a WiFi enabled facility when the meter and data management systems are properly configured.
Data upload	Via data cable	Via data cable or wirelessly

	Predicate	Proposed Device
Characteristic	**Precision Xceed Pro Blood Glucose and β-Ketone Monitoring System**	**Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System**
Cleaning/Disinfection	Cleaning with cloth dampened with water or mild detergent	Disinfection with Dispatch wipes
Barcode scanner	laser	1D/2D camera
Blood glucose assay time	20 sec	5 sec

Performance Studies:

The performance of the meter and test strip were studied in the laboratory and in clinical settings by healthcare professionals. The studies demonstrated that healthcare professionals can obtain blood glucose results that are substantially equivalent to the current methods for blood glucose measurements, which include the predicate device listed above.

Conclusion:

Results of laboratory and clinical testing demonstrate that the performance of the meter and test strip, when used according to the intended use stated above, is acceptable and comparable to the performance of the previously mentioned predicate device for blood glucose testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 27, 2013

Abbott Diabetes Care Inc.
C/O David Lambert
1360 South Loop Road
ALAMEDA CA 94502

Re: K130094
Trade/Device Name: Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, LFR, JQP, JIN
Dated: May 24, 2013
Received: May 28, 2013

Dear Mr. Lambert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130094

Device Name: Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System

Indications for Use:

The Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from the finger, and from venous, arterial and neonatal whole blood, and for the quantitative measurement of β-ketone (beta-hydroxybutyrate) in fresh capillary whole blood from the finger and venous, arterial and neonatal whole blood when used within 30 minutes after collection. The Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of a diabetes control program. This system should only be used with single-use, auto-disabling lancing devices.

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Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System enables automatic transmission of stored data to a data management system using the docking station (optional), a data upload cable (optional), or wirelessly (optional) in a WiFi enabled facility when the meter and data management systems are properly configured.

Prescription Use ___X___	And/Or	Over the Counter Use ___X___
(21 CFR Part 801 Subpart D)		(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-Iyles -S
2013.06.26 09:40:30 -04'00'

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k130094